(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 137 975**
A2

(12) EUROPEAN PATENT APPLICATION

(21) Application number: **84109934.4**

(22) Date of filing: **21.08.84**

(51) Int. Cl.⁴: **A 61 B 5/14**, A 61 B 10/00

(30) Priority: **15.09.83 US 532423**

(43) Date of publication of application: **24.04.85**
Bulletin 85/17

(84) Designated Contracting States: **BE DE FR GB IT NL SE**

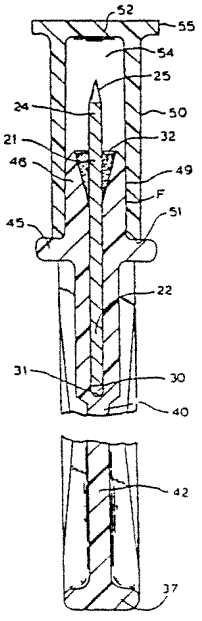
(71) Applicant: **Becton Dickinson and Company, Mack Centre Drive, Paramus New Jersey 07652 (US)**

(72) Inventor: **Nitzsche, Raymond P., 20 Bennington Drive, Edison New Jersey (US)**
Inventor: **Geiger, Kenneth E., 130 Overlook Avenue Apt. 3F, Hackensack New Jersey (US)**

(74) Representative: **Selting, Günther, Dipl.-Ing. et al, Deichmannhaus am Hauptbahnhof, D-5000 Köln 1 (DE)**

(54) Blood lancet assembly.

(57) A blood lancet assembly includes a handle having a distal end and a proximal end to be held by the user. A lancet extends outwardly from the distal end of the handle and terminates in a forward end adapted to penetrate human flesh. A shield having an open end, a closed end and a receptacle therein is removably engaged to the handle so that the forward end of the lancet is positioned within the receptacle. The receptacle is larger than the forward end of the lancet so that the lancet does not contact the shield.



EP 0 137 975 A2

BLOOD LANCET ASSEMBLY

BACKGROUND OF THE INVENTION

1. Field of the Invention. The present invention relates to a blood lancet assembly and more particularly relates to a blood lancet assembly for penetrating living flesh to provide capillary blood for testing.

2. Description of the Prior Art. It is common procedure in hospitals, clinics and doctor's offices to perform tests on blood provided by cutting or puncturing the skin and causing the capillaries of the patient to bleed. The instrument used to cut the capillaries is called a lancet. Lancets are commonly manufactured by stamping and forming the lancet from a sheet metal strip and then sealing it in a flexible package befored sterilizing. The lancet typically includes a shank portion which is formed to produce corregations or ribs, to facilitate holding the lancet, and a planar V-shaped cutting portion. A lancet of this type is shown in U.S. Patent No. 3,046,987 to Ehrlich.

Although efficient for producing capillary blood, the lancet at times causes the user pain and produces more blood than is necessary for some tests. Lay people who have experienced both a hypodermic injection and a lancet puncture for a blood test will usually recite that the lancet is more painful. There are several reasons accounting for the increased pain produced by a lancet. First, a hypodermic needle has ground surfaces that cut and

slice through the flesh while the typical planar lancet point has more of a tendency to puncture, stretch and tear the skin surrounding the puncture area. Also, most hypodermic needles are lubricated to reduce pain and insertion forces. Hypodermic needles are usually produced as an assembly with a rigid needle shield which engages the needle hub and protects the needle point from potential damage during shipping storage and final delivery to the user.

One disadvantage to the hypodermic needle is that it has a lumen for the delivery of medication. At the areas where the surface of the lumen intersects the planes of the ground point, there are formed sharp edges that can actually cut pieces of flesh away as the needle penetrates the flesh. This is undesirable in a lancet application since the removal of flesh will probably increase the amount of time needed for the puncture site to heal.

An improved lancet design is described in U.S. Patent No. 3,358,689 to Higgins. Higgins teaches an integral lancet and package wherein a retainer section and a cap are integrally molded around the lancet covering all surfaces of the lancet point. The integral retainer and cap contains a reduced cross-sectional area portion at the intersection of the retainer and the cap so that rotation of the cap will sever the cap from the retainer section and allow exposure of the lancet point for use. A sterilization process, according to Higgins, is unnecessary since the elevated temperature of

the molten plastic, during the molding process, completely sterilizes the point and adjacent surfaces of the lancet.

Higgins' improvement lies in a rigid cover for the lancet point to protect it during handling. Also, when a flexible package containing a sterile lancet is torn or damaged, the lancet may become contaminated before use. Higgins' rigid package would appear to be more resistant to damage before use and therefore, offers improved protection. Also, with Higgins' integral lancet and package, it is not necessary to pull the lancet out of the package and to risk contamination of the point while doing so.

Nevertheless the integral lancet and package of Higgins has numerous deficiencies. Most noteworthy is that the cap is molded around the lancet point. With this structure, unless the lancet point is symmetric around the longitudinal axis of the lancet, rotation of the cap relative to the lancet point could cause the lancet point to be deflected or damaged by the plastic cap or cause the lancet to cut through the adjacent cap material. The sharper the lancet cutting edges are, the more fragile they are, and the more likely they will be damaged by cap removal. In addition to apparently precluding the use of very sharp edges on the lancet, the Higgins lancet is not readily lubricated because the point is subsequently placed in contact with molten plastic. Also, the Higgins' lancet point cannot be inspected after assembly into the retainer section. Therefore,

any point damage that occurs during the molding procedure will go unnoticed and a potentially defective product will be transmitted to the user. Further, after using a lancet, it is desirable that the point of the lancet be re-covered in order to prevent contamination and/or infection that may result from someone being accidentally cut with the used lancet point. Higgins does not rely on this feature, and the fact that material is destroyed in order to remove the cap suggests that the cap may not stay on the lancet tip if it is repositioned thereon. Finally, the exterior surface of the reduced cross-sectional area in the Higgins device is not sterile and may contact the user's skin during use. This contact by a non-sterile surface can potentially deposit bacteria on the user's skin adjacent to the point of lancet penetration.

Although various forms of lancets have been addressed by the prior art, there is still a need for a simple, straight-forward, easily fabricated disposable blood lancet assembly which offers a sharp cutting point which may be lubricated and inspected during the assembly process and provides a rigid package to protect the cutting point before use wherein the removal of the rigid package will not damage or compromise the cutting point.

SUMMARY OF THE INVENTION

The blood lancet assembly of the present invention comprises a handle having a distal end and

a proximal end to be held by the user. A lancet extends outwardly from the distal end of the handle and terminates in a forward end adapted to cut living animal or human flesh. Also included is a shield having a open end, a closed end and a receptacle therein. This shield is removably engaged with the handle so that the forward end of the lancet is positioned within the receptacle of the shield. The receptacle is larger than the forward end of the lancet so that the lancet is maintained out of contact with the shield.

In accordance with the preferred embodiment of the present invention, a disposable blood lancet assembly comprises a lancet having a rearward end and a forward end shaped to form a point. The lancet point is formed by the intersection of three planes with each of said planes intersecting each other to form three cutting edges. These cutting edges originate at the outside surface of the lancet and terminate at the point. A handle has a proximal end adapted to be held by the user and a distal end connected to the rear end of the lancet so that the forward end of the lancet projects outwardly therefrom. Further, the distal end of the handle includes a raised portion having a side wall. This side wall surrounds the lancet and extends substantially parallel to the longitudinal axis of the lancet. Also provided is a shield having an open end, a closed end and a preferably oblong receptacle therein. This receptacle is longer along its longitudinal axis than the portion of the lancet projecting

outwardly from the handle. The shield is held in removable engagement with the handle by an interference fit between the side wall of the raised portion and the receptacle, wherein the forward end of the lancet is positioned within the receptacle. The shield is removable from the handle without touching the lancet and is replaceable on the handle after use of the lancet.

In accordance with the principles of the present invention, a number of advantages and objectives are attained. Primarily, the present invention provides a simple, straightforward, easily fabricated disposable blood lancet assembly. A sharp cutting point is provided which may be lubricated and inspected during the assembly process. In addition the present lancet assembly includes a rigid package to protect the cutting point before use, wherein the removal of the rigid package should not damage or compromise the cutting point.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of the preferred disposable blood lancet assembly of the present invention;

Fig. 2 is the blood lancet assembly of Fig. 1 illustrating the shield removed and separated from the handle;

Fig. 3 is an enlarged front elevation view of the preferred disposable blood lancet assembly;

Fig. 4 is a cross-sectional view of the blood lancet assembly of Fig. 3 taken along line 4-4;

Fig. 5 is cross-sectional view of the blood lancet assembly of Fig. 3 taken along line 5-5;

Fig. 6 is an enlarged partial side elevation view of the lancet of the preferred disposable blood lancet assembly;

Fig. 7 is a top plan view of the lancet of Fig. 6.

Fig. 8 is an enlarged partial side elevation view of the lancet of the preferred disposable blood lancet assembly taken 90 degrees from the view of Fig. 6; and

Fig. 9 is a top plan view of the lancet of Fig. 8.

DETAILED DESCRIPTION

While this invention is satisfied by embodiments in many different forms, there is shown in the drawings and will herein be described in detail preferred embodiments of the invention with the understanding that the present disclosure is to be considered as exemplary of the principles of the invention and is not intended to limit the invention to the embodiments illustrated. The scope of the invention will be measured by the appended claims and their equivalents.

Adverting now to Figs. 1 through 5, a disposable blood lancet assembly 20 includes a cylindrically shaped lancet 21 having a rearward end 22 and a forward end 24 shaped to form a point 25. Also included is a handle 26 having a planar proximal end

27 and distal end 29. Projecting inwardly into the handle from the distal end toward the proximal end is tubular recess 30 terminating at end 31. Lancet 21 is contained within the tubular recess so that its rearward end is adjacent to the end of the tubular recess. The lancet is held in place in the tubular recess preferably by epoxy 32. It will be apparent to one skilled in the art that numerous constructions can be used to join the lancet and the handle and that the arrangement described above is exemplary of these many possibilities. Also, it is within the purview of this invention to include a one-piece lancet and handle assembly.

It should be noted that the distance between point 25 of the lancet and the distal end of raised portion 46 and/or epoxy 32 is the depth which the lancet can penetrate the user's flesh. Accordingly, the desired depth of penetration of the lancet can be controlled by controlling the above-mentioned distance in the design and manufacture of the lancet assembly.

The handle is planar in configuration in order to provide adequate surface areas for the user to grasp the handle between his finger tips and to control the handle which in turn controls the position of the lancet tip. The desirability of this feature will become apparent hereinafter. The planar proximal end of the handle consists preferably of crossed ribs 34 and 35, perimeter ribs 36, 37 and 39, reduced thickness sections 40, 41, 42 and 44, and distal rib 45. The variations in thicknesses between

the ribs and the reduced thickness sections provide an improved gripping surface over a smooth surface which may tend to become slippery. This is helpful since the planar portion of the handle in the preferred embodiment may be compact in structure with a typical handle measuring approximately 0.3 inch (7.6 mm) wide, by 0.75 inch (19.1 mm) long by 0.1 inch (2.5 mm) thick at the perimeter ribs. Also, the reduced thickness sections lessen the amount of material required to form the handle and therefore the cost. Projecting outwardly from distal rib 45 is cylindrically shaped raised portion 46 which includes circular side wall 49 which surrounds the lancet and is substantially parallel to the longitudinal axis of the lancet.

Assembly 20 further comprises a shield 50 having an open end 51, a closed end 52 and a receptacle 54 having a circularly shaped cross section. The shield is positioned over raised portion 46 and is held in removable engagement thereon. By making the outside diameter of raised portion 46 larger than the inside diameter of receptacle 54, an interference fit is created at interface F between the receptacle surface and side wall 49, so that force must be applied to the shield to disengage it from the handle. The interference fit should be tight enough to keep the shield securely engaged to the handle and to protect the lancet from outside contamination without damaging the parts but must be loose enough to allow easy removal of the shield at the time of use. It should be noted that portions of

raised portion 46 will touch the user's skin during use of the lancet assembly. However, potential for bacterial contamination of the lancet penetration site, by the raised portion, is reduced because shield 50 covers and protects raised portion 46 from contamination after assembly. To facilitate the removal of the shield from the handle, annular end flange 55 has circumferencially oriented scallops 56.

It should be noted that receptacle 54 is preferably longer along its longitudinal axis than the portion of the lancet projecting outwardly from the handle and that the receptacle has a larger inside diameter than the outside diameter of the lancet. This clearance between the lancet at the shield allows the shield to be removed and replaced without touching and possibly damaging the lancet point.

Figs. 6 through 9 depict preferred lancet point 25, as part of the lancet of the present invention. This point is formed by the intersection of planes 59, 60 and 61. The lines of intersection between the planes form cutting edges 64, 65 and 66. Each cutting edge originates at the lancet outside diameter 57 and terminates at leading edge 62 of the point. Preferably, planes 59,60 and 61 are all at the same angle, angle A, with respect to the longitudinal axis of lancet 21. In the preferred embodiment, angle A is approximately 12°. Also, the planes are oriented so that cutting edges 64,65 and 66 intersect and form a point having leading edge 62

approximately at longitudinal axis 63 of the lancet. This point, with its leading edge approximately at the longitudinal axis, is called an axial point.

The cutting edges act as sharp flesh cutting surfaces which cut as the lancet penetrates the skin. A circular point without cutting edges and a sheet metal lancet without ground edges would have a tendency to puncture, stretch and tear the skin as it penetrates producing what is believed to be a more painful incision. Further, a three cutting edge point makes three cuts which can sever capillaries to produce blood while the well-known planar lancet only makes two cuts. Therefore, a two cutting edge lancet would have to make a larger incision to sever the same area of flesh, and produce the same amount of blood, as the preferred point. Accordingly, the preferred axial point is believed to reduce pain and trauma by producing the same amount of blood with a smaller incision.

Unlike a hypodermic needle, as discussed hereinabove, the preferred lancet does not include a lumen with surfaces which can intersect with the planes of the point to form interior cutting edges which can potentially cut away pieces of flesh during penetration.

The present invention also allows the use of a medical grade silicone lubricant on the lancet point. It is known that this lubricant aids in reducing the forces required for the lancet to penetrate the skin and also the pain perceived by the user. Because shield 50 does not touch the lancet,

the lubricant will not be removed or compromised by the act of removing the shield. Along the same lines, the fact that the shield does not touch the lancet allows the edges on the point to be extremely sharp and delicate since they will not be damaged by the removal of the shield.

In the assembly of the instant invention, the shield is not installed until the handle and lancet are assembled. This sequence provides a further advantage in that the point of the lancet may be inspected for any damage that might have occurred during assembly before the shield is installed. Accordingly, a defective product may be eliminated before shipment from the manufacturer.

In use, the user firmly grasps handle 26 with the fingers of one hand and shield 50 in the area of the scallops with the fingers of the other hand. Then the user applies a rotational force to the shield, along with a pulling force, to remove the shield from the raised portion of the handle in order to expose the sharp lancet. The lancet is then quickly thrust toward and into the area of the body where the blood sample is to be taken and promptly removed to allow the blood to flow from the severed capillaries. The shield may then be reinstalled on the handle to cover the lancet and to prevent accidental cuts or infection which may result from inadvertent contact with the exposed lancet. The used lancet assembly is then discarded.

A wide variety of rigid materials is suitable for constructing the handle and shield, however,

thermoplastic materials such as polypropylene and polyethylene are preferred. The choice of epoxy formulation is dictated by the materials and processing conditions chosen for handle and lancet. It is preferred that the lancet be made of medical grade stainless steel unless the handle and the lancet are made in one piece. In the latter case, thermoplastic materials such as ABS, polypropylene and polystyrene are preferred. It is also desirable to apply a medical grade lubricant, such as medical grade silicone lubricant, to the portion of the lancet projecting outwardly from the handle. It is preferred that the lancet should be sterile when used. Accordingly, the materials for all components should be selected for compatability with the sterilization process.

Thus it can be seen that the present invention provides a simple, straight-forward, easily fabricated disposable blood lancet assembly which provides a sharp cutting point which may be lubricated and inspected during the assembly process. Also provided is a rigid shield to protect the cutting point, the lubricant thereon and a portion of the structure surrounding the lancet, before use. The present invention futher allows the removal of the shield without damaging or compromising the cutting point, and allows the subsequent reinstallation of the shield to protect against contamination and accidental cutting.

WHAT IS CLAIMED:

1. A disposable blood lancet assembly comprising:

a lancet having a rearward end and a forward end adapted to penetrate human flesh;

a handle having a proximal end to be held by the user and a distal end connectively associated with said rearward end of said lancet so that said forward end projects outwardly therefrom;

a shield covering said forward end of said lancet projecting from said handle having an open end, a closed end and a receptacle therein, said receptacle being sized so that said forward end is free of direct contact with said shield;

means for holding said shield in removable engagement on said handle with said forward end of said lancet being positioned within said receptacle, said holding means allowing removal of said shield from said handle without said lancet touching said shield, said holding means further allowing replacement of said shield on said handle after use of said lancet.

2. The disposable blood lancet assembly of Claim 1 wherein said holding means includes a raised portion on the distal end of said handle having a side wall surrounding said lancet and being substantially parallel to the longitudinal axis of said lancet, said side wall extending into said receptacle to engage said shield in an interference fit.

3. The disposable blood lancet assembly of Claim 1 wherein said receptacle has a circularly shaped cross section.

4. The disposable blood lancet assembly of Claim 3 wherein said holding means includes a raised portion on the distal end of said handle, said raised portion having a cylindrical side wall surrounding said lancet, said side wall extending into said receptacle to engage said shield in an interference fit.

5. The disposable blood lancet assembly of Claim 4 wherein said shield includes an outside surface adapted to be held between the finger tips of the user so that said shield may be rotated around its longitudinal axis to facilitate removal from said side wall.

6. The disposable blood lancet assembly of Claim 1 wherein said handle includes a flat portion to be held between the fingers of the user.

7. The disposable blood lancet assembly of Claim 1 wherein said forward end of said lancet is shaped to form a point.

8. The disposable blood lancet assembly of Claim 7 wherein said point is formed by the intersection of three planes intersecting each other to form three cutting edges, said cutting edges originating at the outside surface of said lancet and terminating at said point.

9. The disposable blood lancet assembly of Claim 8 wherein said lancet is a cylindrically shaped rod with said point formed thereon.

10. The disposable blood lancet assembly of Claim 8 wherein each of said planes is oriented at the same angle with respect to the longitudinal axis of said lancet.

11. The disposable blood lancet assembly of Claim 8 wherein said planes are oriented so that said point is located approximately at the longitudinal axis of said lancet.

12. The disposable blood lancet assembly of Claim 1 wherein said lancet is made of a material selected from the group consisting of thermoplastic materials and stainless steel.

13. The disposable blood lancet assembly of Claim 1 wherein said handle and said shield are made of thermoplastic material.

14. The disposable blood lancet assembly of Claim 13 wherein said thermoplastic material is selected from the group consisting of polypropylene and polyethylene.

15. A blood lancet assembly comprising:

a handle having a distal end and a proximal end to be held by the user;

a lancet for penetrating living flesh extending outwardly from said distal end and terminating in a forward end; and

a shield having an open end, a closed end and a receptacle therein, said shield removably engaging said handle so that said forward end of said lancet is positioned within said receptacle, said receptacle being larger than said forward end of said lancet so that said lancet does not contact said shield.

16. A disposable blood lancet assembly comprising:

a lancet having a rearward end and a forward end shaped to form a point, said point being formed by the intersection of three planes intersecting each other to form three cutting edges, said edges originating at the outside surface of said lancet and terminating at said point;

a handle having a proximal end to be held by the user and a distal end connectively associated with said rearward end of said lancet so that said forward end projects outwardly therefrom, a raised portion on said distal end having a side wall surrounding said lancet which extends substantially parallel to the longitudinal axis of said lancet; and

a shield having an open end, a closed end and an oblong receptacle therein, said receptacle being longer along its longitudinal axis than said forward end of said lancet projecting outwardly from said handle, said receptacle being larger in a direction

perpendicular to its longitudinal axis than said lancet in a direction perpendicular to its longitudinal axis, said side wall extending into said receptacle to removably engage said shield in an interference fit with said forward end of said lancet positioned within said receptacle wherein said shield is removable from said handle without touching said lancet and said shield is replaceable on said handle after use of said lancet.

17. The disposable blood lancet assembly of Claim 16 wherein said receptacle has a circularly shaped cross section and said side wall being cylindrically shaped.

18. The disposable lancet assembly of Claim 17 wherein said shield includes a outside surface adapted to be held between the finger tips of the user so that said shield may be rotated around its longitudinal axis to facilitate removal from said side wall.

0137975

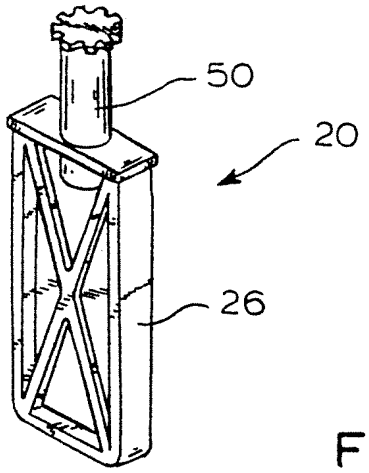


FIG.1

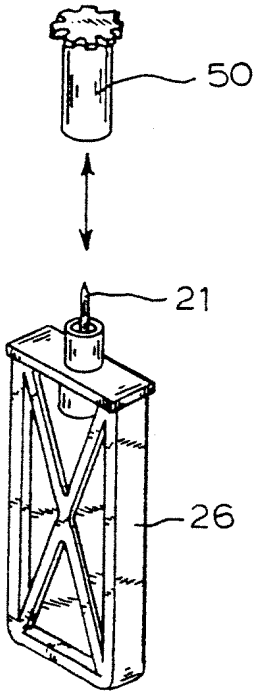


FIG.2

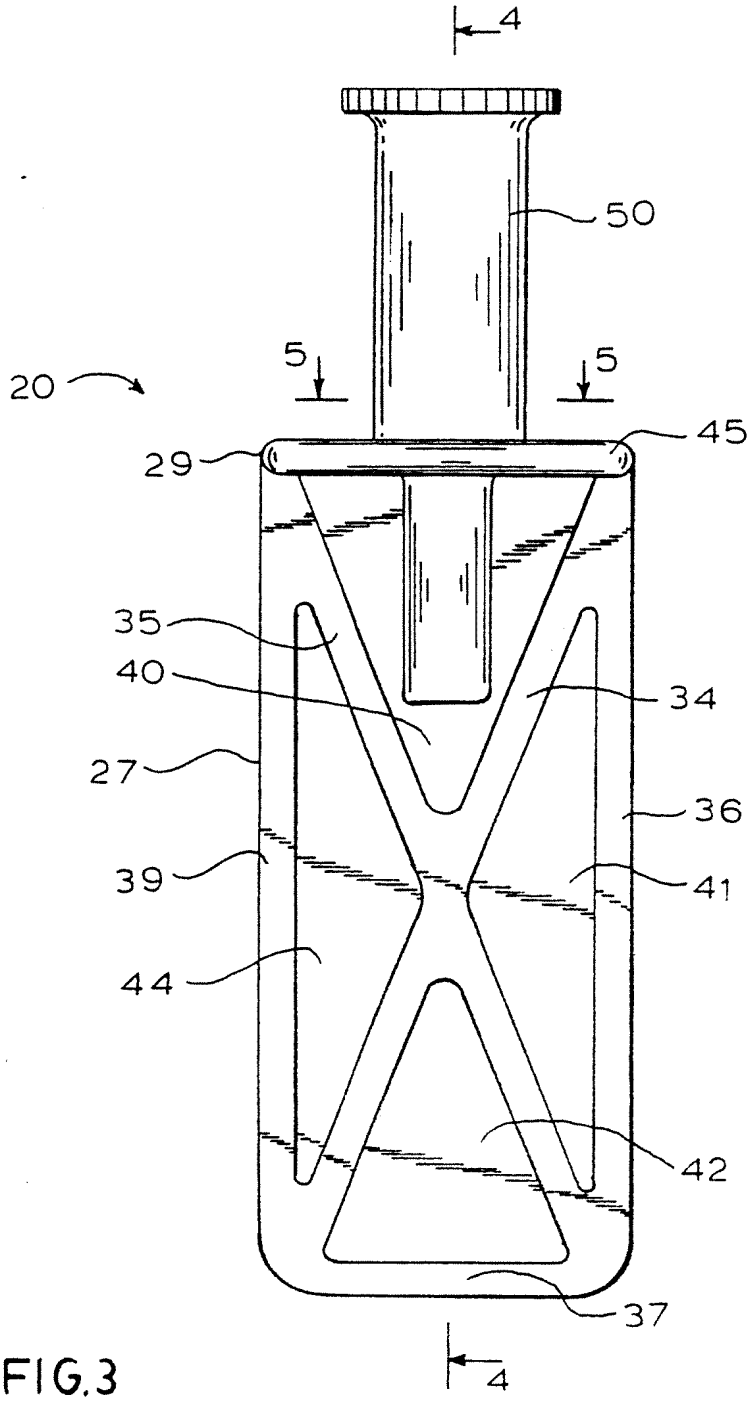


FIG.3

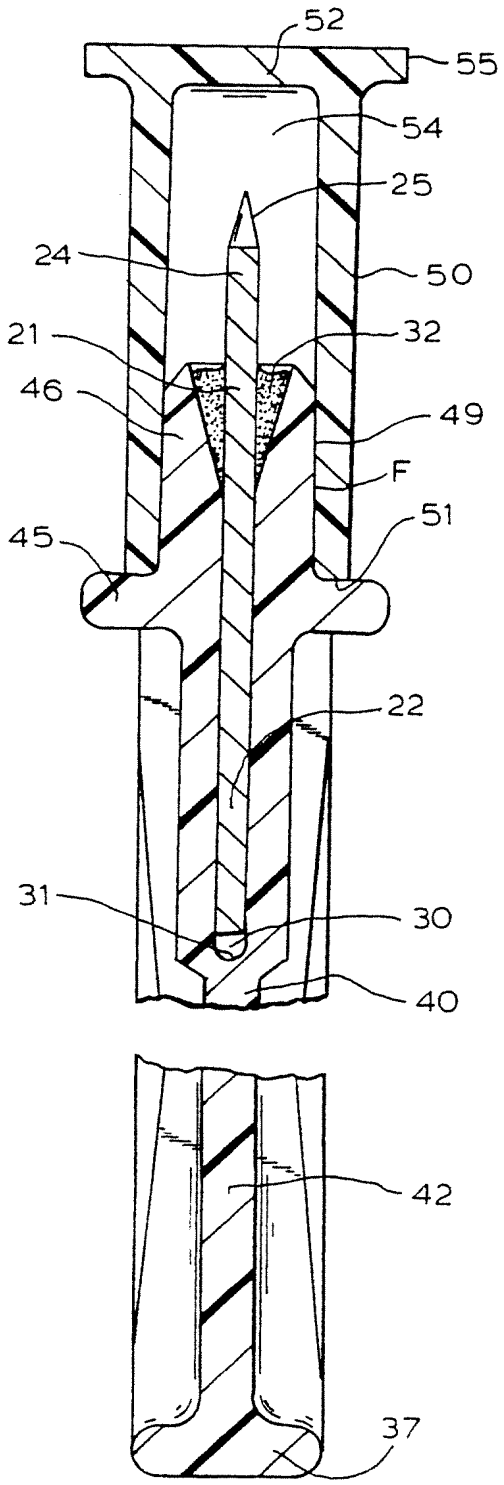


FIG.4

0137975

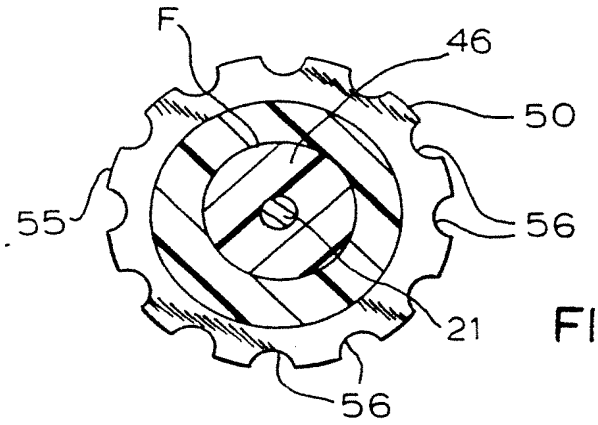


FIG.5

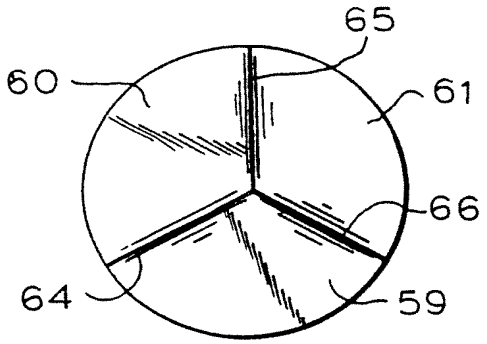


FIG.7

FIG.9

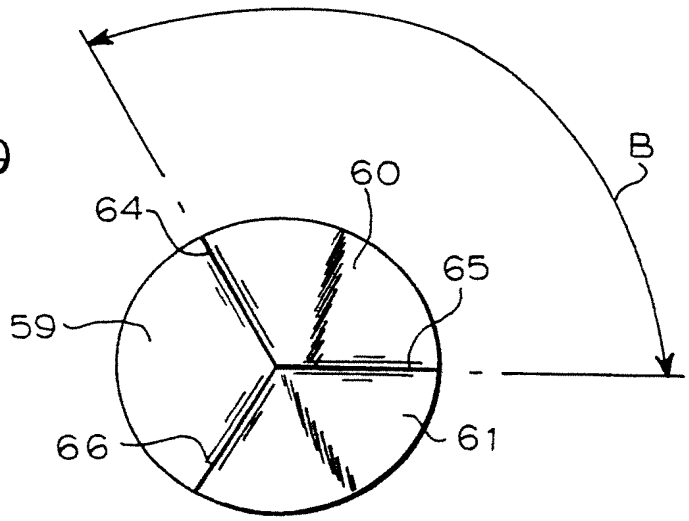


FIG.6

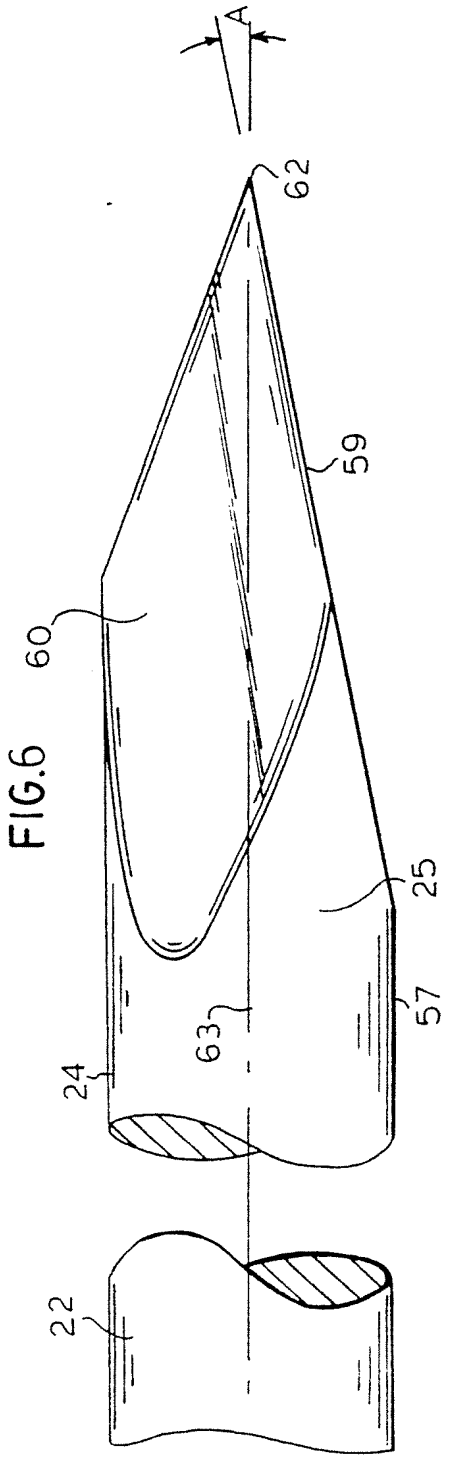


FIG.8